IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** ***Debra Westerfield v. Ethicon, Inc. et al.*** **Case No. 2:14-cv-09748**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFF DEBRA WESTERFIELD'S OPPOSITION TO
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

I. Introduction

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Defendants") move for summary judgment on all of Plaintiff's claims: Negligence (Count I); Strict Liability-Manufacturing Defect (Count II); Strict Liability-Failure to Warn (Count III); Strict Liability-Defective Product (Count IV); Strict Liability-Design Defect (Count V); Common Law Fraud (Count VI); Fraudulent Concealment (Count VII); Negligent Misrepresentation (Count IX); Breach of Express and Implied Warranty (Counts XI and XII); and Violation of Consumer Protection Laws (Count XIII). ECF No. 45 (hereinafter "Mem.").[1]

Defendants' summary judgment motion applies inapplicable legal standards, misconstrues California law, and fails to acknowledge disputed factual issues. Defendants misapplication of California law and fundamental disputed issues of fact preclude granting summary judgment on the challenged causes of action.

II. Plaintiff's Statement of Additional Undisputed Facts

1. Plaintiff filed this case via the Court's ECF system on February 12, 2014.

2. Plaintiff served her initial complaint on Defendants on July 12, 2013, along with a Waiver of Service and Product ID under the Court's Delayed Filing Order in Pretrial Order No. 49. Ex. 1 (Email serving complaint, waiver of service and product ID on July 12, 2013).

3. Defendants rebranded "Prolene Soft Mesh" as "Gynemesh PS" in 2002. Ex. 2 at 754; Ex. 3 (Gynemesh IFU).

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[1] Plaintiff concedes Strict Liability-Manufacturing Defect (Count II) and Strict Liability-Design Defect (Count V) should be dismissed as there are no provisions for these claims under California law.

4. Gynemesh PS is identical in design to Prolene Soft Mesh. Ex. 2 at 755-56, 758; Ex. 4 at 876.

5. Defendants marketed Gynemesh PS to urologists, gynecologists and urogynecologists, and represented Gynemesh PS as created to treat pelvic organ prolapse. Ex. 5 at 16-17 (Elliott Specific Causation Report).

6. Gynemesh PS, Prolift, and the Prolift + M are all "indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse… as mechanical support or bridging material for the fascial defect." Exs. 3, 6, and 7 (Gynemesh PS, Prolift and Prolift + M IFU respectively).

7. On November 8, 2019 Defendants served Plaintiff with expert disclosures under Fed. R. Civ. P. 26, designating a total of fifteen expert witnesses (exclusive of treating physicians). *See* Dkt. No. 28; Dkt No. 49. Defendants designation of fifteen expert witnesses is three times the maximum number allowed by the Court in Pretrial Orders No. 341 and 346. *See* PTO Nos. 341, 346.

III. Standard on Summary Judgment

Summary judgment may be granted only if there is no genuine issue as to any material fact and only if the moving party is entitled to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); Federal Rule of Civil Procedure 56(a). As the non-moving party, Plaintiffs are entitled

> to have the credibility of [their] evidence as forecast assumed, [their] version of all that is in dispute accepted, all internal conflicts in it resolved favorably to [them], the most favorable of possible alternative inferences from it drawn in [their] behalf; and … to be given the benefit of all favorable legal theories invoked by the evidence so considered.

Charbonnages de France v. Smith, 597 F.2d 406, 414 (4th Cir. 1979); *Trull v. Smolka*, 411 Fed. Appx. 651, 658 (4th Cir. 2011). The United States Supreme Court has repeatedly held "the

fundamental principle that at the summary judgment stage, reasonable inferences should be drawn in favor of the nonmoving party." *Tolan v. Cotton*, 134 S. Ct. 1861, 1868 (2014). Because witnesses for both sides have their own perceptions, recollections, and potential biases, "genuine disputes are generally resolved by juries in our adversarial system." *Id*.

On a motion for summary judgment, the Court will not "weigh the evidence and determine the truth of the matter." *Anderson*, 477 U.S. at 249. The Court instead will draw any permissible inference from the underlying facts in the light most favorable to Ms. Westerfield. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

IV. Choice of Law

Plaintiff agrees with Defendants that California substantive law applies. Plaintiff is, and was a resident of the State of California. (Dkt. No. 1 at ¶ 3). Both implant surgeries occurred in the State of California at UCLA Medical Center. (*Id*. at ¶¶ 10-11). And all medical care arising from complications from the mesh, including three revision surgeries, also occurred at the UCLA Medical Center in the State of California.

V. Argument

A. Ms. Westerfield's Prolene Soft Mesh implant was not an off-label use

Defendants claim "[a] manufacturer is not liable for design defect when the device is not used for the purpose for which it was designed, and there can be no failure to warn when the warnings were not directed to the purpose for which it was designed to be used." Mem. at 4. Further, Defendants assert the use of Prolene Soft Mesh by both Dr. Raz and Dr. Rodriguez were "off-label" because "Prolene Soft was not indicated or cleared for surgical treatment of POP." Mem. at 2. In support Defendants cite the Non-Retained Expert Disclosures of Reynaldo Librojo. Mem. at 2. Defendants cite no deposition testimony, expert report, or declaration from Librojo and rely only on defense counsel's vague and ambiguous expert disclosures. *See* Mem. at Ex. C,

pp. 6 (noting Mr. Librojo "*may* testify that the *effective* indication for use of Prolene Soft Mesh was for abdominal wall hernia repair and abdominal wall deficiencies.") (emphasis added). Defendants cannot rely on inadmissible evidence created by defense counsel to support summary judgment. Fed. R. Civ. P. 56(c)(1). Accordingly, Defendants' off-label use argument fails for lack of evidentiary support.[2]

Defendants' argument is unpersuasive for several additional reasons. First, it is at least a disputed question of fact whether Prolene Soft Mesh was indicated to treat pelvic organ prolapse, as the IFU indicates use in "the repair of hernia ***or other fascial defects***" and POP is a fascial defect of the vaginal wall. Ex. 8 (Prolene IFU); Deprest, J., et al. *The biology behind fascial defects and the use of implants in pelvic organ prolapse repair*. Urogynecol J Pelvic Floor Dysfunct. 2006 Jun; 17 Suppl 1. S16-25.[3] Second, years before Ms. Westerfield's implant surgeries, Prolene Soft Mesh was specifically indicated for "tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor" under the marketing-derived brand name Gynemesh PS (Gynemesh Prolene Soft mesh). Ex. 3 (Gynemesh IFU). Defendants admit Gynemesh PS and Prolene Soft Mesh are identical mesh. *See* Ex. 2. Thus, Prolene Soft Mesh was specifically indicated to treat pelvic organ prolapse and such use was not "off-label."

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[2] Moreover, Mr. Librojo is one of *fifteen* expert witnesses (exclusive of treating physicians) Defendants designated, which is three times the number of experts permitted under PTO Nos 341 and 346. Plaintiff has moved to exclude any testimony from these experts, including Mr. Librojo, due to Defendants continued violation of the Court's order. Dkt. Nos. 48-49.

[3] *See also* Dwyer, PL. *Evolution of Biological and Synthetic Grafts in Reconstructive Pelvic Surgery*. Int Urogynecol J Pelvic Floor Dysfunct. 2006 June; 17 Suppl 1:S10-5 (noting in reconstructive pelvic surgery "the rationale for the use of grafts is to reinforce and strengthen pelvic organ repairs similar to the use of grafts to strengthen abdominal repairs.")

1. Prolene Soft Mesh was approved for the repair of fascial defects

Defendants fail to disclose the full list of approved uses for Prolene Soft Mesh, mentioning only hernia repair. In 2000, the FDA approved Prolene Soft Mesh for hernia repairs and treatment of "***other fascial defects*** that require additional reinforcing or bridging material." Ex. 8 (Prolene IFU) (emphasis added). Pelvic organ prolapse is a fascial defect in the vaginal wall. The IFUs for Defendants' other pelvic mesh products confirm this, stating the Gynemesh PS, the Prolift, and the Prolift + M are "indicated for tissue reinforcement and long-lasting ***stabilization of fascial structures of the pelvic floor in vaginal wall prolapse***… as mechanical support or bridging material ***for the fascial defect***." Exs. 3, 6, and 7 (Gynemesh PS, Prolift and Prolift + M IFUs respectively) (emphasis added). In other Gynemesh PS regulatory documents, Ethicon notes surgical treatment of pelvic organ prolapse involves "vaginal wall fascial reconstruction" and the mesh has various characteristics helpful in "repairing fascia defects" during "vaginal wall repair procedures." *See* Ex. 2 at 754. Defendants' other mesh IFUs, including the Gynemesh PS which is identical to the Prolene Soft Mesh, classify pelvic organ prolapse as a ***fascial defect***. Ex. 3. This evidence alone defeats Defendants' off-label use argument.

There is additional evidence Prolene Soft Mesh was widely used in POP and SUI repair. As to Prolene Soft Mesh use in pelvic floor surgeries, Ms. Westerfield's implanting physician, Dr. Shlomo Raz of the UCLA Medical Center, stated:

> The use of polypropylene mesh was, at that time when I did it, used -- we used for many gynecologies in the rectal -- in the rectocele, in the cystocele as free pieces. Was use of sacrocolpopexy -- free pieces. And all people use soft prolene mesh for other applications in the vagina.

Ex. 9 (Heinrech Tr. at 109:19-25). Dr. Raz continued, "soft polypropeylene mesh is used for sacrocolpopexy in the abdomen to fix the roof of the vagina. Is used many centers most years to

repair rectocele and cystocele as free pieces without trocars." Ex. 9 (Heinrech Tr. at 147:18-22). The FDA approved Prolene Soft Mesh for treatment of hernias *and* "other fascial defects that require additional reinforcing," which according to Ethicon's own IFUs, includes pelvic organ prolapse. Using Prolene Soft Mesh to treat Plaintiff's POP and SUI was not "off-label," or at the very least is a disputed question of fact.

2. Prolene Soft Mesh was approved for the repair of POP under the tradename Gynemesh PS

Based on a desire to have a mesh that could be marketed to physicians as one specifically created solely for the surgical repair of pelvic organ prolapse, Ethicon re-named Prolene Soft Mesh as "Gynemesh PS" (Gynemesh Prolene Soft mesh) and marketed the mesh to physicians as "uniquely" designed and "[t]echnically advanced by design" to meet the needs of POP repair surgery, despite the fact it is the same Prolene Soft Mesh that had been on the market for more than two years and was indicated not only for the repair of "fascial defects that require additional reinforcing," which includes pelvic organ prolapse but also for the repair of hernias. Ex. 5 at 16-17 (Elliott Specific Causation Report); Ex. 8 (Prolene Soft Mesh IFU).

With no "new mesh" specifically designed only for the repair of pelvic organ prolapse in the development pipeline, Ethicon re-branded Prolene Soft Mesh as a new, specially designed POP repair mesh called "Gynemesh PS." *See* Ex. 2 at 754 (in the "GYNEMESH* PROLENE Soft Mesh" Design Book, Ethicon states "the objective of this [Gynemesh] project is to provide PROLENE Soft Mesh for use in stabilization of soft tissue repair in Pelvic Floor applications."). In 2002, Ethicon obtained approval for Prolene Soft Mesh in the treatment of "tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor," under the tradename Gynemesh PS. Ex. 3 (Gynemesh IFU). Gynemesh PS is Prolene Soft Mesh, as

Ethicon admits in the Gynemesh PS regulatory filings. In the "GYNEMESH* PROLENE Soft Mesh" Design History Book, Ethicon notes:

- "Gynemesh PROLENE Soft Mesh uses the same material as the Soft PROLENE Mesh." *Id*. at 755;
- "Gynemesh PROLENE Soft Mesh is comprised of the same mesh as PROLENE Soft Mesh." *Id*. at 756;
- "Gynemesh PROLENE Soft Mesh has the same material characteristics as PROLENE Soft Mesh but marketed for a new indication." *Id*. at 758.

Ex. 2 at 755-56, 758. Ethicon used Prolene Soft Mesh as the predicate device for Gynemesh PS stating, "[t]he clinical tissue compatibility of Gynemesh Prolene Soft mesh is essentially equivalent to Prolene mesh since the Gynemesh Prolene Soft mesh is chemically unchanged from Prolene mesh." Ex. 4 at 876; *see also* Ex. 10 at 155 (noting "GYNEMESH PS mesh … is identical in composition, knit and other textile properties to Prolene Soft Mesh."). Prolene Soft Mesh was approved to treat pelvic organ prolapse but simply under the tradename Gynemesh Prolene Soft Mesh.

Changing the name of Prolene Soft Mesh to Gynemesh PS allowed Ethicon to market the mesh to gynecologists, urologists and urogynecologists as "uniquely" designed and "[t]echnically advanced by design" to meet the needs of POP repair surgery, although it is the same mesh. Ex. 5 at 16-17 (Elliott Specific Causation Report). In the Design History Book for "GYNEMESH* PROLENE Soft Mesh," Ethicon admits that the Gynemesh PS "will be offered as a ***new*** product" to physicians for "stabilization in vaginal wall repair procedures" although it was actually an existing product. *See* Ex. 2 at 754 (emphasis added).

In 2005, Ethicon again re-branded Prolene Soft Mesh as the "Prolift," which Ethicon marketed as another specially created mesh system specifically designed solely to treat pelvic organ prolapse. Ex. 6 (Prolift IFU). The Prolift IFU notes the "mesh" component of this new

product was simply pre-cut pieces of Prolene Soft Mesh. *Id*. Ethicon justifies the efficacy of Prolift by citing the efficacy of Prolene Soft Mesh in pelvic floor repairs stating, "[d]iscussions with surgeons who have experience using PROLENE soft mesh for pelvic floor repairs have commented … [that] PROLENE soft mesh is well tolerated and inert." Ex. 10 at 156. Ethicon then cites several favorable studies using Prolene mesh in the treatment of pelvic organ prolapse. *Id*. The above evidence establishes a material question of fact as to whether Prolene Soft Mesh a/k/a "Gynemesh PS," a/k/a "Prolift" was approved to treat POP.

The cases cited by Defendants are inapposite to the facts here. *Huntman, Little* and *Cox* were all cases involving the use of bone screws implanted for pedicle fixation though the screws were approved only for anterior fixation. The bone screws were Class III medical devices "which are subject to the most extensive regulatory controls." *Huntman v. Danek Med.*, 1998 WL 663362, at *5 (S.D. Cal. July 24, 1998). In approving the bone screws for "sacral and anterior (frontal) applications to the spine," the FDA expressly informed Danek Medical that any use of the system for pedicle fixation would be considered investigational or experimental. *Id*. at *6-7. Therefore, unlike here, in *Huntman, Little* and *Cox*, there was a clear delineation that using bone screws for pedicle fixation was not an FDA approved use and was experimental. Prolene Soft Mesh was indicated for the surgical treatment of pelvic organ prolapse either per the indicated use for repairs of "fascial defects that requires additional reinforcing" or for "reinforcement and long-lasting stabilization of fascial structures of the pelvic floor" under the alternate brand name Gynemesh PS.

B. Failure to Warn (Count III), Common Law Fraud (Count VI); Fraudulent Concealment (Count VII); Negligent Misrepresentation (Count IX)

Defendants allege Plaintiff's Failure to Warn and fraud-based claims should be dismissed because "Plaintiff has not deposed her implanting surgeons, Dr. Schlomo Raz and Dr. Larissa

Rodriquez, she cannot meet the burden of proof to show that a different warning would have altered her doctors' decision to implant the Prolene Soft." Mem. at 8. Defendants claim by not deposing Drs. Raz or Rodriquez, Plaintiff "cannot prove legal or specific causation on her failure to warn and other fraud-based claims." *Id*. Defendants' argument is flawed and based on an erroneous assumption causation can be established only via the testimony of implanting physicians. Under California law, causation for a failure to warn claim may be established by either direct or circumstantial evidence. *See Dimond v. Caterpillar Tractor Co*., 65 Cal. App. 3d 173, 183 (1976); *see also Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 435 (1969).

Defendants claim under California's learned intermediary doctrine, "a plaintiff must prove 'not only that no warning was provided or that the warning was inadequate, but also that the inadequacy or absence of the warning caused the [plaintiff's] injury.'" Mem. at 8. Under California law, to meet the proximate cause requirement, a plaintiff need only show "the defendant's failure to warn ***was a substantial factor*** in causing his or her injury." *Huitt v. Southern California Gas Co*., 188 Cal. App. 4th 1586, 1604 (2010) (emphasis added); *see also Conte v. Wyeth, Inc*., 168 Cal. App. 4th 89, 112 (2008). Direct evidence of causation is not required, as Courts in California have long recognized proving causation in a defective products case can be difficult and direct evidence of causation may not exist. *Dimond*, 65 Cal. App. 3d at 183 (noting "Courts have been sensitive to problems faced by consumers or users of defective products in proving defect and proximate cause … the law recognizes that in a products liability case … a plaintiff may, therefore, satisfy his burden of proving defect and causation by circumstantial evidence."); *see also Grinnell,* 274 Cal. App. 2d at 435. Thus, contrary to Defendants' claim, direct testimony from the implanting physicians is not the sole means of proving causation. Under California law causation can be met by circumstantial evidence or "by

expert testimony." *Id.* Here, there is more than sufficient evidence to create a question of fact whether: (1) the implanters knew all the risks associated with Prolene Soft Mesh to treat pelvic organ prolapse; and (2) the implanters would have altered their prescribing conduct had they been apprised of the actual risks of Prolene Soft Mesh.

While Dr. Raz could not give a deposition due his poor health and advanced age (82 years old), he was deposed as the implanting and explanting physician on countless occasions in prior transvaginal mesh cases. Dr. Raz repeatedly testified in these cases, that he and most other members of the UCLA female pelvic medicine group, which he headed, stopped using synthetic mesh in POP procedures and SUI procedures altogether in 2011, after they discovered the seriousness, severity, permanence and frequency of the complications associated with using mesh. Ex. 9 (Heinrech Tr. at 131:7-132:6; 147:13-17); Ex. 11 (Warmack Tr. at 50:19-23). Dr. Raz testified about serious mesh complications not associated with non-mesh surgeries to treat POP and SUI, and how the severity and frequency of those complications were higher than originally expected. Ex. 12 (Hoffman Tr. at 8:24-10:2; 12:14-20; 102:22-104:3).

Testimony from Dr. Raz about the unexpected severity, permanence and frequency of serious complications with mesh, combined with the fact he stopped using mesh for all POP or SUI surgeries in 2011, is sufficient evidence he would not have recommended mesh implants to treat Ms. Westerfield's POP and SUI, had he known these complications and their frequency and severity. Ex. 12 (Hoffman Tr. at 8:24-10:2; 12:14-20; 102:22-104:3). Ex. 9 (Heinrech Tr. at 147:13-17). The only mesh used by Dr. Raz, for either POP or SUI repair, was Prolene mesh and then Prolene Soft Mesh after it came onto the market. Ex. 11 (Warmack Tr. at 43:12-17); Ex. 9 (Heinrech Tr. at 146:9-17; 147:2-9).

Dr. Raz testified it was his practice to always disclose to the patient the risks and complications and provide each patient with written materials about the mesh surgery. Ex. 12 (Hoffman Tr. at 76:11-17). Dr. Raz also testified that simply knowing whether a procedure can cause a potential complication is not sufficient, the physician and patient must also have information about the severity, permanence and frequency of those complications. Ex. 12 (Hoffman Tr. 102:3-18; 102:22-104:3). Given Dr. Raz has testified that his knowledge about the severity and frequency of serious mesh complications changed significantly, there is sufficient evidence to indicate Dr. Raz's informed consent discussion with Ms. Westerfield would have included this additional discussion of the risks associated with mesh had he known this information at the time of Plaintiff's surgery. Ex. 12 (Hoffman Tr. at 8:24-10:2; 12:14-20; 75:13-76:7; 76:11-17).

Dr. Rodriguez was trained under Dr. Raz at UCLA and was on the faculty at UCLA at the time of Ms. Westerfield's second implant surgery in 2006. Ex. 13 (Wicker Tr. at 95:2-96:14) Dr. Raz has repeatedly testified that Dr. Rodriguez and all members of the UCLA female pelvic medicine group, which he headed, stopped using synthetic mesh in POP and SUI procedures after discovering the seriousness, severity, permanence and frequency of complications associated with mesh. Ex. 9 (Heinrech Tr. at 147:13-17); Ex. 14 (Holzerland Tr. at 11:2-9; 36:8-12); Ex. 11 (Warmack Tr. at 39:15-19). Even the UCLA Department of Urology website as of March 2016 confirmed the UCLA Department of Urology does not use mesh to treat POP. Ex. 14 (Holzerland Tr. at 35:18-36:8).

When asked about whether any of his colleagues at UCLA still supported the use of mesh for repair of pelvic organ prolapse, Dr. Raz testified, "[t]he majority abandoned mesh as well."

Ex. 15 (Shennum Tr. at 62:12-15). Dr. Raz further stated, "I am totally against the use of mesh and most of my colleagues are the same." Ex. 15 (Shennum Tr. 60:14-15).

Due to the serious complications associated with the transvaginal implantation of mesh to treat POP, Ethicon even changed the indications for use for Prolene Soft Mesh a/k/a "Gynemesh PS" to abdominal (open or laparoscopic) use only. Ex. 16 (2017 Gynemesh 510k). So, any surgery involving the transvaginal implantation of Prolene Soft Mesh/Gynemesh PS currently would not be an approved use, which is additional evidence there would have been a different outcome in Plaintiff's case had the true risks been known. Drs. Raz and Rodriguez were not aware of the risks associated with Prolene Soft Mesh to treat pelvic organ prolapse and stress urinary incontinence when they implanted the mesh into Ms. Westerfield.

Evidence the implanting physician altered his or her treatment or treatment procedures after learning of the newly discovered risk or increased risk, when there is evidence the plaintiff would not have consented to the implant had she been informed of the risk, is sufficient evidence of causation to survive summary judgment. *See Hill v. Novartis Pharms. Corp*., 2012 U.S. Dist. LEXIS 170650, at *16 (E.D. Cal. Nov. 29, 2012) (finding evidence the prescribing physician revised his patient intake form after learning of the osteonecrosis risk is evidence the physician's prescribing conduct was altered by the additional warnings and will meet the plaintiff's proximate cause requirement at the summary judgment stage).

Defendants' reliance on *Higgins v. Ethicon, Inc*., 2017 WL 2813144 (S.D. W. Va. Mar. 30, 2017) (applying Texas law); *Sowder v. Boston Sci. Corp*., 2015 WL 5838507 (S.D. W. Va. Oct. 5, 2015) (applying Florida law); *Bennett v. Boston Sci Corp*., 2015 WL 2088733 (S.D. W. Va. May 5, 2015) (applying West Virginia law) and *Mullins v. Ethicon, Inc*., 2017 WL 345865 (S.D. W. Va. Jan. 20, 2017) (applying West Virginia law) are inapposite as none are based on

applying California law and it's more flexible standard of proving causation in a failure to warn case.

At the summary judgment stage, "a party does not necessarily have to produce evidence in a form that would be admissible at trial, as long as the party satisfies the requirements of Federal Rules of Civil Procedure 56." *Fraser v. Goodale*, 342 F.3d 1032, 1036 (9th Cir. 2003). At summary judgment the trial court does "not focus on the admissibility of the evidence's form" but rather "on the admissibility of its contents." *Id*. The Court will consider the evidence if any deficiencies in the evidence can be overcome at trial. *Id*. at 1037; *see also Fonseca v. Sysco Food Servs. of Ariz., Inc.,* 374 F.3d 840, 846 (9th Cir. 2004). Here, there is abundant testimony from Dr. Raz in other transvaginal mesh cases demonstrating he was not aware of the complications associated with synthetic mesh at the time of Ms. Westerfield's implant, but that he later learned of these facts and stopped using synthetic mesh altogether. Ex. 9 (Heinrech Tr. at 147:13-17); Ex. 14 (Holzerland Tr. at 11:2-9; 36:8-12); Ex. 12 (Hoffman Tr. at 8:24-10:2; 12:14-20; 102:22-104:3). This evidence meets California's proximate cause requirements or at minimum raises disputed questions of fact. Based on this testimony, Defendants cannot show that no jury could reasonably find for Plaintiff on this issue, making summary judgment improper.

C. Strict Liability-Design Defect (Count V), Strict Liability-Defective Product (Count IV)

Defendants argue summary judgment is proper on Plaintiff's Strict Liability-Design Defect claim because "California does not recognize a cause of action for strict liability design defect in cases involving drugs and medical devices." Mem. at 9. Plaintiff concedes that California does not recognize a cause of action for Strict Liability–Design Defect (Count V) for medical device cases. However, California does recognize design defect claims under a

negligence theory against medical implant manufacturers. *Brown v. Superior Court*, 44 Cal. 3d 1049, 1061 (1988); *see also Artiglio v. Superior Court*, 22 Cal. App. 4th 1388, 1392 (1994).

Defendants also move to dismiss Plaintiff's Strict Liability-Defective Product claim (Count IV). In support Defendants state, "A search of California law does not reveal there to be any such cause of action." Mem. at 9. Defendants fail to meet their burden or present any evidence sufficient to support dismissal of this claim.

D. Negligence (Count I) and Negligent Misrepresentation (Count IX)

Defendants move for summary adjudication of Plaintiffs' negligence-based claims because "[t]he negligence-based warning and manufacturing defect claims rely on the same series of facts as their strict liability counterparts and fail for the same reason—lack of causation." Mem. at 10. As set forth in Section V.B., *supra*, Plaintiff has presented sufficient evidence of causation and at minimum has raised disputed questions of fact.

E. Common Law Fraud (Count VI), Fraudulent Concealment (Count VII) and Negligent Misrepresentation (Count IX)

Defendants contend Plaintiff's Common Law Fraud, Fraudulent Concealment, and Negligent Misrepresentation claims "should be dismissed as duplicative of the failure to warn claim" [Mem. at 10], and separately under the learned intermediary doctrine because "Plaintiff cannot satisfy the element of reliance because all of the representations run from the manufacturer to the prescribing physician. Therefore, these claims fail for lack of proof of reliance." Mem. at 11. Defendants' argument the fraud-based claims "should be dismissed as duplicative" disregards California law, which allows separate fraud-based claims arising from a manufacturer's failure to disclose all risks associated with a medical device. *See Conte v. Wyeth*, 168 Cal. App. 4th 89, 103-05 (2008). Such claims are not subsumed into strict liability and negligent failure to warn claims in California.

Defendants fare no better with their no "proof of reliance" argument. Mem. at 11. As set forth in Section V.B., *supra*, Dr. Raz and Dr. Rodriguez (who worked under Dr. Raz at UCLA) were not aware of the true risks of the transvaginal repair of POP and SUI using mesh at the time of Plaintiff's implant surgeries and would not have recommended or used mesh if they had known the true risks. The evidence in Section V.B., *supra*, establishes reliance and causation and at minimum raises disputed questions of fact.

F. Express Warranty (Count XI) and Implied Warranty (Count XII)

Defendants contend Ms. Westerfield's express and implied warranty claims "should be dismissed as duplicative of the failure to warn claim." Mem. at 11. Defendants cite no case law, nor offer any argument to support this assertion that express and implied warranty claims are subsumed into a plaintiff's strict liability and negligent failure to warn claims in cases involving medical devices under California law. Defendants other warranty arguments fare no better.

1. The statute of limitations do not bar Plaintiff's warranty claims

Defendants argue Plaintiff's warranty claims are barred by the statute of limitations because Plaintiff failed to file her lawsuit within four years of "when tender of delivery [was] made." Mem. at 11. Under California law, a plaintiff's claim for express and implied warranty accrues "when he discovers or should have discovered the breach." Cal. Comm. Code § 2725(4); *Mills v. Forestex Co*., 108 Cal. App. 4th 625, 642 (2003) (finding plaintiff had to file breach of warranty claims "within four years from the date they discovered, or should have discovered, the [product] was not performing properly."). Contrary to Defendants' assertion, the discovery rule does apply to warranty claims under California law. *See Mills*, 108 Cal. App. 4th at 642-43 (applying discovery rule to warranty claims); *Yi v. BMW of N. Am*., 2018 WL 3359016, at *17-18 (C.D. Cal. May 24, 2018); Cal. Comm. Code § 2725(4) (noting "this section does not alter the law on tolling of the statute of limitations.").

When a plaintiff "discovered or reasonably should have discovered the facts for purposes of the delayed discovery rule is a question of fact unless the evidence can support only one reasonable conclusion." *Ovando v. Cty of Los Angeles*, 159 Cal. App. 4th 42, 61 (2008). Here, Ms. Westerfield testified she did not attribute her injuries to the mesh until 2011 or 2012, which is well within the statute of limitations period for her warranty claims. Ex. 17 at 7 (Plaintiff Fact Sheet). Defendants' request for summary judgment on this issue should be denied.

2. Pre-suit notice was not required

Defendants move for summary judgment on Plaintiff's warranty claims "[b]ecause Plaintiff failed to give Ethicon presuit notice," Mem. at 11-12. But pre-suit notice need not be given to Defendants here since the product was not purchased by Plaintiff directly from the Defendants. *Greenman v. Yuba Power Prods. Inc.*, 59 Cal. 2d 57, 61 (1963) (when a plaintiff receives the allegedly defective product via a third-party instead of directly from the manufacturer, the plaintiff need not provide the manufacturer with pre-suit notice of the breach); *see also Sanders v. Apple, Inc*., 672 F. Supp. 2d 978, 989 (N.D. Cal. 2009); *McVicar v. Goodman Global, Inc*., 1 F. Supp. 3d 1044, 1057 (C.D. Cal. 2014); *Mui Ho v. Toyota Motor Corp*., 931 F. Supp. 2d 987, 993-95 (N.D. Cal. 2013).

In *Keegan*, for example, the plaintiff sued an automobile manufacturer for breach of express warranty. *Keegan v. American Honda Motor Co*., 838 F. Supp. 2d 929 (C.D. Cal. 2012). Honda argued, like Defendants do here, the plaintiff had to provide notice and an opportunity to cure to the dealership before suing. Applying the California Supreme Court's decision in *Greenman*, the *Keegan* court rejected Honda's argument; "[U]nder California law," explained the court, "a consumer need not provide notice to a manufacturer before filing suit against them." *Keegan,* 838 F. Supp. 2d at 950-51; *accord Sanders*, 672 F. Supp. 2d at 989; *McVicar*, 1 F. Supp. 3d at 1057. Here, pre-suit notice was not required.

3. Privity is not required for Plaintiff's warranty claims

Defendants further contend Plaintiffs warranty claims should be dismissed because under California law "[i]n the implantable medical product context, a patient lacks the privity required to establish a claim for breach of . . . warranty." Mem. at 12 (citing *Currier v. Stryker Corp.*, 2011 WL 489501, at *4 (E.D. Cal. Oct. 13, 2011). However, Defendants' misapprehend the decision in *Currier*. The district court simply noted that no privity existed between the plaintiff and defendant in the "implantable medical product context" and generally such privity is required to bring a warranty claim. *Currier*, 2011 WL 489501, at *4. While privity is generally required under California law to assert express or implied warranty claims, several important exceptions apply here. First, for claims alleging a breach of the implied warranty of merchantability under the California Commercial Code, there is an exception to the privity requirement when the goods are intended to be and are introduced into the body of a human. *See Arnold v. Dow Chemical Co*., 91 Cal. App. 4th 698 (2001); *see also In re Aredia & Zometa Prods. Liab. Litig.,* 2009 U.S. Dist. LEXIS 72098, at *9-10 (M.D. Tenn. Aug. 13, 2009) (applying California law); Cal. Com. Code § 2314.

There is also no privity requirement for implied warranty claims under the Song-Beverly Act which attaches an implied warranty of merchantability to every retail sale of consumer goods in California. *Keegan*, 838 F. Supp. 2d at 944; Cal. Civ. Code § 1792; *Gonzalez v. Drew Industries,* 750 F. Supp. 2d 1061, 1072-73 (C.D. Cal. 2007). Therefore, Defendants' privity argument has no application as to Plaintiff's implied warranty claims under either the Commercial Code or Song-Beverly Act.

Moreover, where the plaintiff is an intended third-party beneficiary of the product, courts have dispensed with any privity requirement. *See Keegan*, 838 F. Supp. 2d at 947; *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 754 F.

Supp. 2d 1145, 1185 (C.D. Cal. 2010) ("[W]here a plaintiff pleads that he or she is a third-party beneficiary to a contract that gives rise to the implied warranty of merchantability, he or she may assert a claim for the implied warranty's breach."). Here, Plaintiff is the intended beneficiary, i.e., recipient of the mesh product.

VI. Conclusion

For the above reasons, Defendants' Motion for Summary Judgment should be denied, except as to Plaintiff's claims for Strict Liability-Manufacturing Defect (Count II), Strict Liability-Design Defect (Count V).

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 3, 2020, I electronically filed the foregoing Opposition to Defendants Motion for Summary Judgment with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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